Randomized controlled within-subject evaluation of digital and conventional workflows for the fabrication of lithium disilicate single crowns. Part I: digital versus conventional unilateral impressions

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DOI: https://doi.org/10.1016/j.prosdent.2016.05.007

JPD-15-765

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ABSTRACT

Statement of problem. Trials comparing the overall performance of fully digital and conventional workflows in reconstructive dentistry are needed.

Purpose. The purpose of the first part of this randomized controlled clinical trial was to determine whether optical impressions produce different results from conventional impressions with respect to time efficiency and patient and operator perceptions of the clinical workflow.

Material and methods. Three digital impressions and one conventional impression were made in each of 10 participants according to a randomly generated sequence. The digital systems were Lava C.O.S. (Lava), iTero (iTero), and Cerec Bluecam (Cerec). The conventional impression was made with the closed-mouth technique and polyvinyl siloxane material. The time needed for powdering, impressions, and interocclusal record was recorded. The patient and the clinician perception of the procedures were rated by means of visual analogue scales (VAS). The paired *t* test with Bonferroni correction was applied to detect differences (α=.05/6=.0083).

Results. The mean total working time ±standard deviation amounted to 260 ±66 seconds for the conventional impression, 493 ±193 seconds for Lava, 372 ±126 seconds for iTero, and 357 ±55 seconds for Cerec. The total working time for the conventional impression was significantly lower than that for Lava and Cerec. With regard to the working time without powdering, the differences between the methods were not statistically significant. The patient rating (very uncomfortable=0, comfortable=100) measured 61 ±34 for conventional

impression, 71 ±18 for Lava, 66 ±20 for iTero, and 48 ±18 for Cerec. The differences were not statistically significant. The clinician rating (simple=0, very difficult=100) was 13 ±13 for the conventional impression, 54 ±27 for Lava, 22 ±11 for iTero, and 36 ±23 for Cerec. The difference between the conventional impression and Lava and between iTero and Lava were statistically significant.

Conclusions. The conventional impression was more time effective than the digital impressions. In terms of patient comfort, no differences were found between the conventional and the digital techniques. With respect to the clinician perception of difficulty, the conventional impression and the digital impression with iTero revealed more favorable outcomes than the digital impression with Lava.

CLINICAL IMPLICATIONS

For the restoration of single posterior teeth, optical impressions have no advantages over the closed-mouth impression technique with polyvinyl siloxane material regarding time efficiency and patient preference. This conclusion cannot be generalized to patients with multiple abutment teeth or implants in need of complete-arch impressions.

INTRODUCTION

Improvements in intraoral optical impression systems and computer-assisted design and computer-assisted manufacturing (CAD/CAM) technologies have increased the digitalization of the clinical and the technical procedures in reconstructive dentistry. Intraoral scanning and CAD/CAM technology is considered a viable alternative to the conventional workflow. CAD/CAM generated tooth- and implant-supported prostheses appear to exhibit survival rates similar to those of conventionally fabricated prostheses.[1,2]

It has been advocated that a fully digital workflows for prosthodontics present several benefits over the conventional pathway, such as improved patient acceptance, higher

accuracy, real-time imaging, facilitated communication, and increased time effectiveness.[3,4]An in vitro study evaluating the time effectiveness of implant impressions found that digital impressions required less time than the conventional technique using an elastomeric material.[5] A recent clinical investigation compared the digital and the conventional workflow for the fabrication of implant-supported crowns with respect to the treatment time.[6] It was concluded that the digital pathway may shorten the duration of the overall clinical treatment and technical production process achieving a beneficial cost-benefit ratio. Another clinical study comparing the time efficiency of digital and conventional impressions for the fabrication of tooth-supported restorations[7] found that the quadrant optical impressions are significantly less time consuming than complete-arch conventional impressions.

As far as patient preferences are concerned, 2 clinical studies compared digital impressions of implants with the conventional procedure with polyether.[8,9] The investigators found overall patient preference to be significantly in favor of the digital approach. However, to date, the authors have identified no controlled clinical studies investigating the digital workflow in reconstructive dentistry with respect to the overall treatment time and treatment efforts, the subjective preferences, and the quality of the resulting prosthesis.

The present randomized controlled clinical trial was designed to compare the overall performance of 3 different digital workflows and 1 conventional workflow for the fabrication of tooth-supported crowns in the posterior regions, starting from the impression to the delivery of the crowns. The purpose of the first part of the study was to test whether optical unilateral impressions used to fabricate single-unit crowns in posterior jaw regions differ from conventional closed-mouth unilateral impressions with respect to time effectiveness and patient and operator perceptions of the clinical workflow.

MATERIAL AND METHODS

This study was designed as a randomized controlled clinical trial including within-subject comparison of 4 different impression methods. The study was performed at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Zurich, Switzerland. The trial was approved by the local ethical committee (Kantonale Ethik-Kommission, Zurich, Switzerland) (Ref. KEK-ZH-Nr. 2011-0102/5).

Ten participants in need of 1 single crown were included in the study. The participants had to fulfill the following inclusion criteria: ≥ 18 years of age, full-mouth plaque scores (FMPS) and full-mouth bleeding scores (FMBS) < 25%, no active periodontal disease, need for a tooth-supported crown in posterior regions (first premolar to second molar), study abutment tooth without need for additional treatment, and adjacent and antagonist teeth healthy or sufficiently restored. A signed informed consent was obtained from all the individuals participating in this study.

If 2 or more teeth per participant were available, fulfilling the inclusion criteria, one was selected by throwing a die. The sequence of the impression procedures under investigation was allocated according to a computer-generated randomization list. The impression sequences were concealed by means of sealed envelopes until the time of the clinical procedure that required the tooth impression.

Three clinicians (G.B., I.S., S.M.) performed the clinical treatments. The clinicians were experienced with the tested digital impression systems and ceramic CAD/CAM restorations. Before the study initiation, the clinicians attended a training session to review the study protocol to standardize the clinical procedure and to calibrate the assessment techniques.

The study abutment teeth were prepared following the guidelines for complete ceramic crowns (Sturzenegger B et al. Swiss Dental Journal 2000;110:131-9 . The preparation comprised a shoulder finish line with rounded inner angles, tapering of the axial wall by

approximately 10 degrees, and rounding all edges. At the buccal aspect, the finish line was located 0.5 mm subgingivally. After tooth preparation, an interim crown was fabricated with an autopolymerizing composite resin (Protemp 3 Garant; 3M ESPE). At the subsequent clinical appointment, 3 digital (test) and 1 conventional (control) impressions were made in each of the 10 participants. The sequence of the impressions was randomly generated. After the removal of the interim crown and the cleaning of the study tooth, the randomization envelope was opened. The gingival displacement cords (Ultrapak; Ultradent Products Inc) were placed according to the double-cord technique.[10]

Three digital systems for intraoral optical impression and occlusal registration were tested: Lava C.O.S. (3M ESPE) (Lava), iTero (Align Technology Inc) (iTero), and Cerec Bluecam (Sirona Dental Systems GmbH) (Cerec). Before scanning with Lava or Cerec, a titanium dioxide powder was applied to the tooth surface (Lava Powder for Chairside Oral Scanner; 3M ESPE or Vita Cerec Powder with Cerec Propellant; VITA Zahnfabrik). Quadrant scans were made and the scan sequences were chosen according to the manufacturers' guidelines. The conventional unilateral impression and the interocclusal record were performed simultaneously by using the closed-mouth (triple-tray or check-bite) technique.[11] Polyvinyl siloxane (A-silicone) light- and regular-body materials (President; Coltène/Whaledent AG) were used for the impression by applying the simultaneous mixing technique.

The quality of the digital and the conventional impressions was controlled by evaluating the imprint precision of the study abutment tooth, of the interproximal surfaces at the adjacent teeth, and of all the occlusal surfaces. The impressions not fulfilling the quality criteria resulted in additional digital scans or remakes of conventional impressions. The procedures used for the transfer and the processing of digital data, and the fabrication of models and crowns will be described in a subsequent publication.

The time needed for the powdering, the impressions, and the interocclusal record was assessed. The time needed for the conventional closed-mouth impression was recorded from the beginning of the mixing procedure up to the end of the tray removal from the patient's mouth. The duration of the digital impression and the occlusal registration corresponded to the intraoral scanning time. In addition, the number of impression remakes was recorded. After obtaining an impression fulfilling the quality criteria, the patient's and the clinician's perceptions of the impression procedure were rated by means of a visual analog scale (VAS). The VAS consisted of a 100-mm horizontal line, which was confined at both ends with anchor terms. The patients were asked to rate the comfort of the impression (anchor terms: very uncomfortable = 0, comfortable = 100). The clinicians were asked to rate the difficulty of the impression (anchor terms: simple = 0, very difficult = 100) and the comfort of the impression (anchor terms: very uncomfortable = 0, comfortable = 100). The VAS answers were converted in a numerical format ranging from 0 to 100 for statistical analysis.

Descriptive statistics was computed for all the variables with software (SPSS Statistics v20; IBM Corp). The data distributions were represented with boxplots and the data were reported by using means, standard deviations (SD), ranges, and 95% confidence intervals. The assumption of normality was evaluated with the Kolmogorov-Smirnov test. All the results presented a normal distribution. The paired *t* test with Bonferroni correction was applied to detect differences between the impression systems (α=.05/6=.0083).

RESULTS

Six women and 4 men participated in the study with a mean age of 51.2 years (range: 31 to 63 years). Study teeth were 7 maxillary molars, 1 mandibular molar, 1 maxillary premolar, and 1 mandibular premolar.

In 9 of 10 participants the conventional impression time was lower than the other groups. The mean total working time ±SD was 260 ±66 seconds for conventional impression,

493 ±193 seconds for Lava, 372 ±126 seconds for iTero, and 357 ±55 seconds for Cerec. The differences between conventional impression and Lava (*P*=.008), and between conventional impression and Cerec (*P*=.004) were statistically significant. A conventional impression remake was needed in 1 of 10 participants. Additional scans were made in 1 of 10 participants with Lava, in 4 of 10 participants with iTero, and in 2 of 10 participants with Cerec.

The mean impression/scanning time ±SD without powdering was 260 ±66 seconds for conventional impression, 439 ±196 seconds for Lava, 372 ±126 seconds for iTero and 292 ±50 seconds for Cerec. The differences between the treatment options were not statistically significant (*P*>.008).

The patient rating of the impression comfort rated by means of VAS ±SD was 61 ±34 for conventional impression, 71 ±18 for Lava, 66 ±20 for iTero and 48 ±18 for Cerec. The differences among the groups were not statistically significant (*P*>.008).

When the clinician perception of impression difficulty was assessed, the mean results ±SD were 13 ±13 for conventional impression, 54 ±27 for Lava, 22 ±11 for iTero, and 36 ±23 for Cerec. The difference between conventional impression and Lava (P = .008), and between iTero and Lava (*P*=.008) were statistically significant. The mean clinician rating of the impression comfort ±SD measured 88 ±15 for conventional impression, 53 ±20 for Lava, 77 ±17 for iTero and 56 ±24 for Cerec. The difference between conventional impression and Lava was statistically significant (*P*=.006).

DISCUSSION

In this study the conventional procedure for unilateral impressions was more time effective than the digital techniques with intraoral scanners. Nevertheless, in terms of patient comfort no differences were found between the conventional and the digital impressions. With respect

to the clinician perception of difficulty, the conventional impression and digital impression with iTero revealed significantly better results in comparison to digital impression with Lava.

The present results differed from the findings of a previous study investigating the time effectiveness of digital and conventional impressions. In that in vitro trial, 30 predoctoral students performed conventional and optical impressions on a customized model presenting a single implant.[5] Digital impression with iTero resulted in a faster procedure than silicone conventional impressions. Longer preparation, working, and remake time were needed to complete an acceptable conventional impression. The difficulty was lower for the digital impression compared with the conventional ones when performed by students. The differences in the total working time and in the perception of difficulty between this in vitro study and the present clinical trial can be explained by the fact that only experienced clinicians participated in the present clinical investigation. Moreover, there were differences in the protocol that was applied for the conventional impression. In the present trial, a unilateral closed-mouth technique was applied for the conventional impression, allowing the impression of both jaws and the occlusal registration in a single step.

A recent clinical study compared the time efficiency of digital and conventional impressions for the fabrication of tooth-supported restorations.[7] In 25 participants, 17 single crowns and 8 3-unit partial fixed dental prostheses (FDPs) were fabricated. Each participant underwent an optical impression with Lava C.O.S. and a conventional impression with polyether. For single crowns, the optical impression involved a quadrant scan capturing the prepared tooth, the opposing quadrant, and the buccal aspect of these quadrants in the intercuspal position. For 3-unit FDPs, the scanning protocol consisted of a complete-arch scan of the prepared teeth, the opposing jaw, and the left and right buccal aspects with the teeth in the intercuspal position. The conventional workflow always involved a complete-arch polyether impression of the prepared teeth, an alginate impression of the opposing jaw, and an occlusal record with composite resin. For single crowns, a quadrant optical scan required on

average 5 minutes less time in comparison to a complete-arch conventional impression. For 3-unit FPDs, a complete-arch optical scan took on average 1.5 minutes less than a complete-arch conventional impression. The differences in the results between this clinical study and the present trial can be explained by the differences in the protocols used for the conventional impression. In the present trial, a unilateral closed-mouth technique with polyvinyl siloxane material was applied for the conventional impression.

A recent in vitro trial evaluated the difficulty level and the operator's perception of 30 dental students and 30 experienced clinicians when making digital and conventional implant impressions.[12] The difficulty level of optical impressions was similar between the student and the clinician groups. The conventional impression was perceived as more difficult by the student group than by the clinician group. The student group favored the digital impression technique, whereas the clinician group did not show any significant preference over either impression technique. The investigators pointed out that students with no previous exposure to conventional or digital implant impression making were included in the study to investigate the efficiency of different treatment options in an objective and nonbiased manner.

A previous clinical study assessed the patient perception of difference between conventional impressions with polyether and digital impressions with iTero for implant restorations in the posterior jaw.[9] Thirty participants underwent both impression procedures in the same session. The operating clinician had considerable experience in conventional impression-making procedures. In the majority of the procedures, the conventional impression required significantly less time. The overall preference of the patients was in favor of the digital approach, despite the fact that patients perceived the duration of digital impressions more negatively. A recent randomized controlled trial compared the patient-centered outcomes during digital and conventional impressions.[8] In a crossover study design, complete-arch intraoral scanning with the iTero system and polyether impressions were performed on 20 participants in need of a single implant-supported crown. The investigators

found the overall patient preferences to be significantly in favor of the digital approach. The digital technique was more time efficient than the conventional procedure. The differences in the patient perception between these trials and the present investigation may be explained by differences in the protocols applied for conventional impressions (impression material, impression duration, size of the impression tray) and for digital impressions (need for powdering, need for tooth-support during the scanning procedure, scanning sequence). Moreover, in the present study, 4 different impression procedures were tested on each participant. This fact may have hampered the assessment of patient perception in comparison with the previous investigations that tested 1 digital and 1 conventional impression procedure.

The small sample size is a limitation and must be taken into account when interpreting the findings of the present study. Another shortcoming is that the time needed to prepare the impression procedure (setting up the impression material and trays and starting the computer system) was not assessed. Moreover, the issue of investigating conventional and digital impression systems is that the research findings are material-, procedure-, and system-specific. For example, an impression with a closed-mouth technique tray cannot be compared with conventional complete-jaw impressions. Because more rapid and easier-to-use scanners will be available in the future, the findings of the present study cannot be generalized to future digital impression systems.

The conclusions of the present investigation are limited to patients in need of single tooth-supported crowns in the posterior region and cannot be generalized to patients in need of complete-arch impressions of multiple teeth and implants. Based on the findings of the present trial, optical impressions for the restoration of single posterior teeth do not offer advantages over conventional silicone impressions with respect to time efficiency and patient preference. Future clinical research should assess the digital and the conventional workflows for the impression and restoration of multiple teeth and implants.

CONCLUSIONS

Within the limitations of the present clinical study, the following conclusions were made:

1. For unilateral impressions made by experienced clinicians, the shortest working time was achieved by the conventional impression with silicone.
2. With regard to working time without powdering, the differences between the conventional and digital impressions were not statistically significant.
3. No differences were found in patient comfort between the conventional and digital impressions.
4. The conventional impression and the digital impression with iTero were considered easier than the digital impression with Lava.

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TABLES

Table 1. Time needed for impression and occlusal registration

	Lava				**iTero**				**Cerec**				**Conventional**			
	Mean ± SD	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****
Powdering time (sec)	54 ± 14	44 - 64	30 - 71		-	-	-		66 ± 37	39 - 92	29 - 155		-	-	-	
Impression/ Scanning time (sec)	439 ± 196	299 - 580	234 - 760	iTero .142 Cerec .036 Conv. .029	372 ± 126	282 - 462	256 - 680	Lava .142 Cerec .055 Conv. .043	292 ± 50	256 - 327	222 - 358	Lava .036 iTero .055 Conv. .029	260 ± 66	212 - 307	185 - 426	Lava .029 iTero .043 Cerec .029
Total time (sec)	493 ± 193	356 - 631	295 - 813	iTero .017 Cerec .044 Conv. .008†	372 ± 126	282 - 462	256 - 680	Lava .017 Cerec .678 Conv. .043	357 ± 55	318 - 397	251 - 453	Lava .044 iTero .678 Conv. .004†	260 ± 66	212 - 307	185 - 426	Lava .008† iTero .687 Cerec .004†

SD, standard deviation; 95% CI, 95% confidence interval; *, results of paired *t* test; †, statistically significant

Table 2. Impression procedure: patient and operator perceptions

	Lava				**iTero**				**Cerec**				**Conventional**			
	Mean ± SD	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****	**Mean ± SD**	**95% CI**	**Range**	***P****
Patients' preference: Comfort	71 ± 18	58 - 84	48 - 98	iTero .463 Cerec .026 Conv. .374	66 ± 20	51 - 80	32 - 98	Lava .463 Cerec .008† Conv. .700	48 ± 18	34 - 61	19 - 75	Lava .026 iTero .008† Conv. .363	61 ± 34	37 - 85	2 - 97	Lava .374 iTero .700 Cerec .363
Clinicians' preference: Difficulty	54 ± 27	35 - 73	2 - 89	iTero .008† Cerec .123 Conv. .008†	22 ± 11	14 - 30	5 - 41	Lava .008† Cerec .167 Conv. .193	36 ± 23	20 - 53	4 - 73	Lava .123 iTero .167 Conv. .030	13 ± 13	3 - 23	0 - 39	Lava .008† iTero .193 Cerec .030
Clinicians' preference: Comfort	53 ± 20	39 - 67	33 - 88	iTero .011 Cerec .781 Conv. .006†	77 ± 17	65 - 89	43 - 96	Lava .011 Cerec .097 Conv. .225	56 ± 24	39 - 73	16 - 96	Lava .781 iTero .097 Conv. .012	88 ± 15	77 - 98	48 - 100	Lava .006† iTero .225 Cerec .012

SD, standard deviation; 95% CI, 95% confidence interval; *, results of paired *t* test; †, statistically significant